Reference number(s)
6596-A

SPECIALTY GUIDELINE MANAGEMENT

NIKTIMVO (axatilimab-csfr)

POLICY

I. INDICATIONS

The indications below including FDA-approved indication and compendial uses are considered a covered benefit provided that all the approval criteria are met and the member has no exclusions to the prescribed therapy.

FDA-Approved Indication
Niktimvo is indicated for the treatment of chronic graft-versus-host disease (cGVHD) after failure of at least two prior lines of systemic therapy in adult and pediatric patients weighing at least 40 kg.

All other indications are considered experimental/investigational and not medically necessary.

II. CRITERIA FOR INITIAL APPROVAL

Chronic graft-versus-host disease (cGVHD)
Authorization of 12 months may be granted for treatment of cGVHD when all of the following criteria are met:
A. The member has had at least two prior lines of systemic therapy that failed to produce the desired response AND
B. The member weighs at least 40 kg.

III. CONTINUATION OF THERAPY

Authorization of 12 months may be granted for continued treatment in members requesting reauthorization for an indication listed in Section II when there is no evidence of unacceptable toxicity or disease progression while on the current regimen.

IV. REFERENCES

1. Niktimvo [package insert]. Wilmington, DE: Incyte Corporation; August 2024.